**UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MINNESOTA**

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| Biomedical Device Consultants & Laboratories of Colorado, LLC, | : | |
| | : | |
| Plaintiff, | : | Civ. 17-cv-03403 DWF/SER |
| | : | |
| v. | : | |
| TA Instruments – Watters LLC, | : | |
| | : | |
| Defendant. | : | |

**DECLARATION OF KRISTEN BILLIAR IN SUPPORT OF DEFENDANT'S OPPOSITION TO PLAINTIFF'S MOTION FOR PRELIMINARY INJUNCTION**

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I, Kristen Billiar, declare as follows:

1. I am currently the Department Head of the Biomedical Engineering Department and Professor in the Biomedical Engineering and Mechanical Engineering Departments at Worcester Polytechnic Institute. I submit this Declaration in support of TA Instruments – Waters LCC's ("TA Instruments") opposition to Biomedical Device Consultants & Laboratories of Colorado, LLC's ("BDC") motion for preliminary injunction. In particular, I submit this Declaration to provide relevant background information regarding the technology at issue in U.S. Patent No. 9,186,224 (the '224 Patent) and U.S. Patent No. 9,237,935 (the '935 Patent); to set forth my opinions from the perspective of a person of ordinary skill in the pertinent field; and to address certain positions presented in the Declaration of Michael Girard in Support of Motion for Preliminary Injunction.

## I. Qualifications, Experience and Publications

2. The following is a brief summary of my background and qualifications. My background and qualifications are more fully set out in my curriculum vitae (CV), attached as Exhibit 1.

3. I have at least 22 years' experience in the biomedical engineering and medical device fields. I am currently a professor and department head of the Biomedical Engineering Department, and an affiliated professor in the Department of Mechanical Engineering at Worcester Polytechnic Institute (WPI), where my responsibilities include developing and teaching courses for both the Biomedical and Mechanical Engineering Departments. Additionally, I am an adjunct professor in the Department of Surgery at the University of Massachusetts Medical School, Worcester, MA.

4. Prior to my current position, I was a staff engineer at Organogenesis, Inc., from 1998 to 2002, where my responsibilities included designing and testing blood vessel substitutes and testing systems.

5. I obtained a Ph.D. in Bioengineering from the University of Pennsylvania in 1998, where my dissertation investigated the effects of glutaraldehyde treatment and mechanical fatigue on bioprosthetic aortic valves. I also obtained a Master of Science in Bioengineering from the University of Pennsylvania in 1992. Additionally, I obtained a Bachelor of Science in Mechanical Engineering from Cornell University in 1991.

6. I currently teach undergraduate and graduate courses concerning mathematical modeling of physiologic materials and mechanisms, including biomechanics, biofluids, and I also teach courses on medical device development, including biomedical engineering design. In addition, I oversee a laboratory at WPI that performs predominantly grant-funded research concerning tissue mechanics and mechanobiology. The laboratory includes graduate, Ph.D., and post-doctorate level researchers. Also, I supervise teams of undergraduate and graduate students with research projects, including implantable medical prosthetic and medical device development and testing.

7. As shown in my CV, I have authored or coauthored over 70 publications, including publications concerning mechanical evaluation of implantable cardiovascular devices subjected to accelerated testing. I also serve as a peer reviewer for scholarly publications and journals, including the Cardiovascular Engineering and Technology journal and the Journal of Biomechanical Engineering for the American Society of Mechanical Engineers.

8. I was also elected as a Fellow of the American Society of Mechanical Engineers (ASME) in 2013, where I have served on the executive board of the bioengineering division for

5 years. Also, I was elected as a Fellow of the American Institute for Medical and Biological Engineering (AIMBE) in 2016, where I serve as a co-chair of review committee for grants in biomedical engineering section for American Heart Association.

9. I have received $10.75 million worth of grant funding from various organizations, including the American Heart Association, National Institutes of Health, National Science Foundation, and Whitaker Foundation, for my investigations into technology at the forefront of the bioengineering field.

10. I am an inventor on eight patents in the bioengineering field.

## II. Compensation

11. I am being compensated for my time spent on this matter at the rate of $450.00 per hour spent testifying in deposition, hearing, or at trial, and at the rate of $250.00 per hour for all other services performed in connection with this matter, plus reasonable expenses. My compensation is not related to the outcome of this action and I have no financial interest in this case.

## III. Prior Testimony

12. During the past four years, I have testified as an expert in the following case: *In re AlloDerm*, Case No. 295 Superior Court of New Jersey, Law Division: Middlesex County; *M. Simineri et al. v. LifeCell Corp.*, Docket No.: MID-L-5972-11 CM.

## IV. Materials Considered

13. The testimony that I offer is based on the person of ordinary skill as I have defined it below. In preparing this declaration, I have considered each of the following documents:

- **Exhibit 1:** Curriculum Vitae;
- **Exhibit 2:** U.S. Patent No. 9,186,224 (the '224 Patent);
- **Exhibit 3:** Excerpts from the prosecution history of the '224 Patent (prosecuted as U.S. Application No. 14/523,104);
- **Exhibit 4** U.S. Patent No. 9,237,935 (the '935 Patent);
- **Exhibit 5:** Excerpts from the prosecution history of the '935 Patent (prosecuted as U.S. Application No. 14/137,313);
- **Exhibit 6**: U.S. Patent No. 8,584,538 (the '538 Patent, which is related to the '224 and '935 patents);
- **Exhibit 7**: Excerpts of the 2005 edition of ISO 5840;
- **Exhibit 8**: U.S. Patent No. 4,682,491 to Pickard ("Pickard");
- **Exhibit 9**: U.S. Patent No. 3,208,448 to Woodward ("Woodward");
- **Exhibit 10**: U.S. Patent No. 4,546,642 to Swanson ("Swanson");
- **Exhibit 11**: Iwasaki *et al.*, *Implications for the Establishment of Accelerated Fatigue Test Protocols for Prosthetic Heart Valves*, Artificial Organs Vol. 26 No. 5:420-429 (May 2002) ("Iwasaki"); and
- **Exhibit 12**: Reul *et al.*, *Durability/Wear Testing of Heart Valve Substitutes*, J Heart Valve Dis Vol. 7, No. 2: 151-157 (March 1998) ("Reul").

By referring to my curriculum vitae, I mean that I also relied upon my years of experience in the field. A copy of each of the foregoing exhibits is attached. Although Exhibits 3 and 5 are only excerpts of prosecution histories, I considered the relevant prosecution histories in their entirety and only attach the portions that I cite. I also considered, and cite, the Declaration of Michael Girard in Support of Motion for Preliminary Injunction. I did not attach a copy of the Declaration of Michael Girard in Support of Motion for Preliminary Injunction because I understand the Court has a copy of that Declaration.

## V. The Patents-in-Suit and Relevant Technology

14. The '224 and '935 Patents are in the same patent family, both claiming priority to U.S. Provisional Application No. 61/158,185 filed on March 6, 2009. The '224 and '935 Patents are both entitled "Fatigue Testing System for Prosthetic Devices," and both name Benjamin McCloskey, Craig Weinberg, and Steve Weinberg as inventors. The '224 and '935 Patents generally relate to cyclic testing of cardiovascular devices such as a valved prosthetic device.

15. The '224 Patent contains seven total claims, including only one independent claim and six dependent claims. I understand that, in its motion for a preliminary injunction, BDC alleges infringement of claims 1 and 6 of the '224 Patent.

16. Claims 1 and 6 of the '224 patent are quoted below:

> **Claim 1.** A method for operating an accelerated cyclic test system for evaluating a valved prosthetic device comprising
>
> driving a test system fluid cyclically above a normal physiological rate, at an accelerated pulsed rate of greater than 200 beats per minute within the test system;
>
> storing a volume of test system fluid in an excess volume area during a system driving stroke that opens the valved prosthetic device; and
>
> releasing the stored volume of test system fluid during a return stroke that closes the valved prosthetic device.
>
> **Claim 6.** The method of claim 1, further comprising compressing a volume of a compressible gas with the volume of test system fluid to provide a spring force counter to and in response to a pressure on the test system fluid when the volume of test system fluid is stored in the excess volume area.

17. The '935 Patent contains thirteen total claims, including only one independent claim and twelve dependent claims. I understand that, in its motion for a preliminary injunction, I understand that BDC alleges infringement of claims 1 and 9 of the '935 Patent.

18. Claims 1 and 9 of the '935 patent are quoted below:

**Claim 1.** A device for accelerated cyclic testing of a valved prosthetic device comprising

a pressure source configured to drive a test system fluid cyclically within the device above a normal physiological rate, at an accelerated pulsed rate of greater than 200 beats per minute within the device; and

a pressurizable test chamber for containing the test system fluid and further comprising a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source;

a fluid return chamber positioned on a second side of the valved prosthetic device;

a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber; and

an excess volume area capable of operating at the accelerated pulsed rate, wherein the excess volume area is in fluid communication with the fluid return chamber providing a volume for storing a volume of a test system fluid when the test system fluid is under compression.

**Claim 9.** The device of claim 1, wherein the excess volume area comprises a compliance chamber defining a cavity within the fluid return chamber.

## VI. Level of Skill in the Art

19. Having reviewed the '224 and '935 Patents and their prosecution histories, in my opinion, the relevant field is testing of cardiovascular devices.

20. In my opinion, the person of ordinary skill in the art would have at least (a) a bachelor's degree in biomedical engineering, or a related field, such as mechanical engineering or biomechanical engineering, who also has at least 3-5 years of experience with cardiovascular devices; or (b) an advanced degree in the same areas of academic study with at least 1-2 years of corresponding experience.

21. I have been informed that the relevant time period for my analysis in forming my opinions is prior to the earliest identified priority date, March 6, 2009. I believe that I understand what the person of ordinary skill in the art would have known as of March 6, 2009, based upon

my experience, which includes my doctoral thesis research defended in 1998, and my years of teaching biomechanics.

## VII. Validity Principles

22. Counsel for Defendants have explained the legal standards that apply in the Litigation. I explain the standards that I have applied in reaching my opinions below, and in some instances, I may expand upon these standards further when describing the basis for my opinions in this report.

23. I understand that a patent contains a specification, which contains a description of the invention claimed by the patentee. I also understand that the specification concludes with one or more numbered sentences, which are known as the patent 'claims.' I understand that the claims define the boundaries of the patent's invention - i.e., the boundaries of the patent's protection.

24. I also understand that the claims of patent are to be construed as having the ordinary meaning that a person of ordinary skill in the art (identified above) would ascribe to them in view of the specification, unless the inventor has provided a specific definition in the specification or the file history of the patent. I also understand that the prosecution history can inform meaning of patent claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in course of prosecution, making the scope of the claim narrower than it would otherwise be.

25. I understand that patents are presumed valid, and that each claim of a patent is presumed valid independently of the validity of other claims. However, I also understand that the fact that the United States Patent and Trademark Office has granted a patent does not mean that any invention claimed in that patent deserves protection.

26. I am aware that a patent claim may be invalid even though it was initially approved by the United States Patent and Trademark Office. As described below, I am aware that a patent claim may be invalid due to a variety of bases.

27. I understand that a patent claim may be invalid as anticipated.

28. Specifically, I have been informed that in order to be entitled to patent protection, an invention must be new. I understand that inventions are new when the product or process covered by the claim have not been made, used, or disclosed before. Like other grounds of invalidity, I understand that anticipation is determined on a claim-by-claim basis.

29. I am aware that a patent claim may be anticipated for a variety of reasons. I am aware that an invention is anticipated, if it was known to or used by others in the United States before the date of the invention. I am aware that an invention is known when the information about it was readily accessible to the public. I am aware that an invention is anticipated if it was already patented or described in a printed publication anywhere in the world before the date of invention.

30. I have also been informed that a claim is invalid as anticipated if all of the requirements of that claim were present in a single previous device or method that was known of, used, or described in a single previous printed publication or patent. To anticipate the claim, the prior art does not have to use the same words, but all of the requirements of the claim must have been disclosed, either stated expressly or implied to a person of ordinary skill in the art in the technology of the invention, so that looking at that one reference, that person could make and use the claimed invention.

31. I understand that a patent claim may be invalid as obvious.

32. That is, I am aware that a patent claim is invalid if the invention of the claim

would have been obvious to a person of ordinary skill in the art of the patent. For patent claims having filing dates before March 16, 2013, obviousness should be assessed at the time of the invention. For patent claims having filing dates on or after March 16, 2013, obviousness should be assessed at the time just before the patent's effective filing date.

33. I understand that this inquiry considers: (1) the level of ordinary skill in the art that someone would have had at the pertinent time; (2) the scope and content of the prior art; (3) and any differences between the prior art and the claimed invention. I am aware that one should not use hindsight when considering whether a claim is obvious.

34. I also understand that an invention may be obvious if at the pertinent time there was a reason that would have prompted a person of ordinary skill in the art to combine the known elements in a way the claimed invention does, taking into account such factors as (1) whether the claimed invention was merely the predictable result of using prior art elements according to their known function(s); (2) whether the claimed invention provides an obvious solution to a known problem in a relevant field; (3) whether the prior art teaches or suggests the desirability of combining elements claimed in the invention; (4) whether the prior art teaches away from combining elements in the claimed invention; (5) whether it would have been obvious to try the combinations of elements, such as when there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions; and (6) whether the change resulted more from design incentives or other market forces. To find an invention obvious, the prior art must provide a reasonable expectation of success.

## VIII. Cardiovascular device design principles and related testing considerations at the time of the invention

35. Prior to use in a human body, cardiovascular devices are tested in environments that simulate a circulatory system. That is, cardiovascular devices are tested in environments that attempt to replicate pulsatile flow conditions. Exh. 8, Pickard, 1:6-14.

36. Testing systems for cardiovascular devices, such as valved prosthetic devices, were known prior to March 6, 2009, the earliest claimed priority date. I know that these testing systems were known as early as March 2009, as I reported on bioprosthetic heart valve durability using such testing systems in my doctoral thesis in 1998 entitled "A structurally guided constitutive model for aortic valve bioprostheses: Effects of glutaraldehyde treatment and mechanical fatigue."

37. One of the ways these testing systems attempt to simulate the circulatory system is by using a liquid test fluid, such as deionized (DI) water or phosphate buffered saline (PBS) solution, as a blood substitute in a flow circuit. Like blood, the liquid test fluid is considered an incompressible fluid.

38. Some test systems involve a closed flow circuit (i.e., not open to atmosphere). In order for a pump to displace a volume of incompressible test fluid in a closed flow circuit, the flow circuit must include a volume where the displaced fluid can be received or stored.

39. While ISO 5840 imposes design specifications and minimum performance specification for heart valve prostheses, ISO 5840 does not provide a definition of "accelerated" cyclic testing as testing at a rate of greater than 200 beats per minute.

## IX. Invalidity of '224 Patent

40. During the prosecution of the '224 patent, the Patent Office concluded that U.S. Patent No. 4,682,491 to Pickard ("Pickard") "teaches a method for operating an accelerated

cyclic test system for evaluating a valved prosthetic device." Exh. 3, p. 31 (Non-Final Rejection, March 20, 2015). The Patent Office also concluded that "Pickard teaches … storing volume of test system fluid in an excess volume area." Exh. 3, p. 31 (Non-Final Rejection, March 20, 2015). The Patent Office further concluded that "Pickard teaches … releasing the stored volume of test system fluid during a return stroke that closes the valved prosthetic device." Exh. 3, p. 31 (Non-Final Rejection, March 20, 2015). In other words, the Patent Office concluded that Pickard disclosed the method of claim 1 as it was originally presented to the Patent Office. Except with respect to the term "accelerated," BDC does not appear to have challenged any of those Patent Office's conclusions. I agree with the Patent Office's conclusion that Pickard discloses a method for operating a cyclic test system for evaluating a valved prosthetic device, as stated in claim 1 of the '224 patent. And I also agree that Pickard discloses a system that features the storing and releasing steps of claim 1 of the '224 patent.

41. During the prosecution of the '224 patent, the Patent Office concluded that "Pickard teaches compressing a volume of compressible gas with the volume of test system fluid to provide a spring force counter to and in response to a pressure on the test system fluid when the volume of test system fluid is stored in the excess volume area." Exh. 3, p. 32 (Non-Final Rejection, March 20, 2015). I agree with the Patent Office's conclusion that Pickard teaches claim 6 of the '224 patent.

42. BDC sought to distinguish Pickard on the basis that claim 1 is directed to a method for operating an "accelerated" test system. *See* Exh. 3, p. 26 (Applicant-Initiated Interview Summary, May 14, 2015). But BDC was unable to convince the Patent Office that the inclusion of the word "accelerated" in the preamble of rejected claim 1 distinguished Pickard. *See* Exh. 3, p. 26 (Applicant-Initiated Interview Summary, May 14, 2015).

43. So in response to the Patent Office rejection, BDC amended claim 1 to require "driving a test system fluid … at an accelerated pulsed rate of greater than 200 beats per minute." Exh. 3, p. 11 (Amendment, June 17, 2015). In the same document, BDC argued that the amended claim distinguished Pickard.

44. Before BDC amended claim 1, the '224 application did not disclose any particular number of beats per minute for testing.

45. Based on BDC's amendment and its argument, the Patent Office allowed the claims of the '224 patent. The Patent Office stated that it allowed the claims because Pickard failed to specifically teach "an accelerated cyclic test system for evaluating a valved prosthetic device with a pulsed rate of greater than 200 beats per minute in independent claim 1 when combined with the limitations of an excess volume area (which is a term of art …) and its location …." Exh. 3, p. 7 (Notice of Allowance, September 17, 2015).

46. BDC sought to distinguish its claims from Pickard, which discloses a 'real-time' test system according to BDC, on the basis that it claimed a method for operating an "accelerated" test system. *See* Exh. 3, pp. 14, 17 (Amendment, June 17, 2015).

47. ISO 5840 does not define "accelerated" testing as testing at greater than 200 beats per minute.

48. According to Table 1 of ISO 5840, a heart valve substitute operational environment includes a heart rate up to 200 beats per minute. BDC used that information in ISO 5840 to persuade the Patent Office that "accelerated" means at greater than 200 beats per minute. Exh. 7, ISO 5840:2005, p. 12.

49. Pickard teaches that its "object of the present invention to provide a method and apparatus for testing of a prosthetic heart valve under individualized test conditions simulating a

specific human circulatory environment into which the valve may be placed." Exh. 8, Pickard, 2:57-62. Like the '224 application, Pickard did not disclose any particular number of beats per minute for testing. But Pickard teaches a heart valve testing system operated under individualized test conditions.

50. The Patent Office did not consider U.S. Patent No. 3,208,448 to Woodward during prosecution of the '224 patent. Woodward teaches about an artificial heart pump circulation system. Woodward teaches that it was known in the art that a normal physiological heart rate for a normal young adult includes a range of from 60 bpm (resting) to 160-180 bpm (heavy exercise) to 240-270 bpm (short exhaustive work). Exh. 9, Woodward, 13:38-49. In other words, Woodward discloses that a normal physiological range can go up 270 bpm.

51. In view of Woodward, one of skill in the art would have been motivated to configure Pickard's system and use Pickard's method to test heart valves at greater than 200 bpm to simulate the 240-270 bpm of a normal young adult during short exhaustive work.

52. In my opinion, it would not have challenged one of ordinary skill in the art before 2009 to operate Pickard's test system at 240-270 bpm given the minimum frequency range including 200 bpm in ISO 5840, and one of ordinary skill in the art would have had a reasonable expectation that Pickard's method would work at such a rate. At the relevant time, one of ordinary skill in the art would have reasonably expected be successful using Pickard's methods at up to the 270 bpm, disclosed in Woodward.

53. BDC argued that Pickard's system compliance served a different purpose than the excess volume area of the '224 patent claims. Exh. 3, p. 14 (Amendment, June 17, 2015). But Picard's compliance element involved "compressing … compressible gas" as in claim 6 of the

'224 patent. The function of Picard's compliance element and claim 6's "compressing … compressible gas" are the same action, and have the same effect.

54. During the prosecution of the '224 patent, BDC suggested that compliance chambers had not been used in heart valve accelerated durability testers. *See* Exh. 3, pp. 17-18 (Amendment, June 17, 2015). But the 2005 edition of ISO 5840 suggested the use of a compliance chamber in heart valve durability testing. *See* Exh. 7, ISO 5840:2005, Annex F, pp. 44-45. And heart valve accelerated durability testers were known to use compliance. *See*, e.g. Exh. 12, Reul, and Exh. 11, Iwasaki.

55. The Patent Office may not have allowed the '224 patent if it had been provided all of the relevant information in ISO 5840, such as ISO 5840's recommendation of the use of compliance chambers in accelerated heart valve durability testing.

56. The Patent Office may not have allowed the '224 patent if it had told that compliance had been used in accelerated testing of prosthetic heart valves.

57. In my opinion, the Patent Office would not have accepted a "rate … greater than 200 beats per minute" as a distinguishing limitation if it had understood that Pickard's goal of simulating a specific human circulatory environment would include testing at rates above 200 bpm, in accordance with Woodward's disclosure that normal rates include 240-270 bpm.

58. In my opinion, claims 1 and 6 of the '224 patent are obvious over Pickard in view of Woodward's disclosure of a normal heart rate greater than 200 bpm.

**X. Invalidity of '935 Patent**

59. During prosecution of the '935 Patent, BDC filed a preliminary amendment requiring the claimed device to have "a pressure source configured to drive a test system fluid cyclically within the device . . . at an accelerated pulsed rate of greater than 200 beats per

minute." Exh. 5, p. 14 (Preliminary Amendment, October 15, 2015).

60. In an Interview with the Patent Office on October 29, 2015, Dr. Weinberg "discussed differences between accelerated and non-accelerated prosthetic device testers." Exh. 5, p. 12 (Examiner-Initiated Interview Summary, November 12, 2015). Dr. Weinberg also "discussed the limits of non-accelerated compliance chambers as they relate to the claimed excess volume area." Exh. 5, p. 12 (Examiner-Initiated Interview Summary, November 12, 2015). BDC later reported that, in the Interview, Dr. Weinberg spoke "technically to the[] issues." Exh. 5, p. 2 (Comments, December 9, 2015).

61. Apparently in the Interview, the Patent Office proposed to amend the claims. Exh. 3, pp. 9-10 (Notice of Allowance, November 12, 2015). On the day of the Interview and the next day, BDC agreed to amend the claims to require that the excess volume area be "capable of operating at the accelerated pulsed rate." Exh. 5, pp. 9-10 (Notice of Allowance, November 12, 2015).

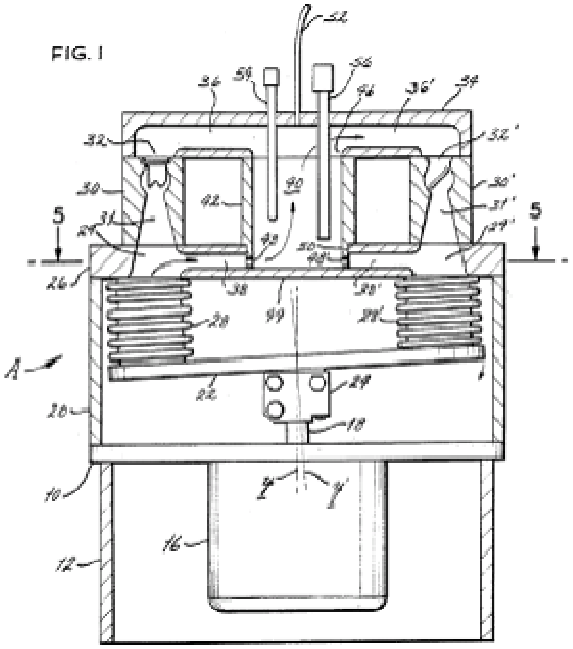
62. Thereafter, the Patent Office concluded that "the best prior art of record Pickard et al. (US 4,682,491) and Swanson et al. (US 4,546,642) fail to specifically teach the invention as claimed." Exh. 5, p. 10 (Notice of Allowance, November 12, 2015). The Patent Office explained that "[t]he specific limitation of an accelerated cyclic testing device with an excess volume area capable of operating at the accelerated pulsed rate of greater than 200 beats per minute … distinguish the present invention from the combined prior art." Exh. 5, p. 10 (Notice of Allowance, November 12, 2015).

63. During prosecution of the '935 application, BDC did not point out any disclosure that would lead one of skill in the art to understand that the excess volume area in Pickard or in Swanson would not be capable of operating at greater than 200 beats per minute. I found no

disclosure that would lead one of skill in the art to understand that the excess volume area in Pickard or in Swanson would not be capable of operating at greater than 200 beats per minute.

64. U.S. Patent No. 4,546,642 to Swanson ("Swanson") discloses "Accelerated Heart Valve Testing Apparatus and Methods." Exh. 10, Swanson, Title. Swanson discloses apparatus for cyclic durability (fatigue) testing of prosthetic heart valves. Exh. 10, Swanson, Abstract.

65. Swanson illustrates System A, a device for accelerated cyclic testing of heart valves, in Figures 1 through 5. Exh. 10, Swanson, Brief Description of the Drawings. For reference, Figure 1 of Swanson is copied below.



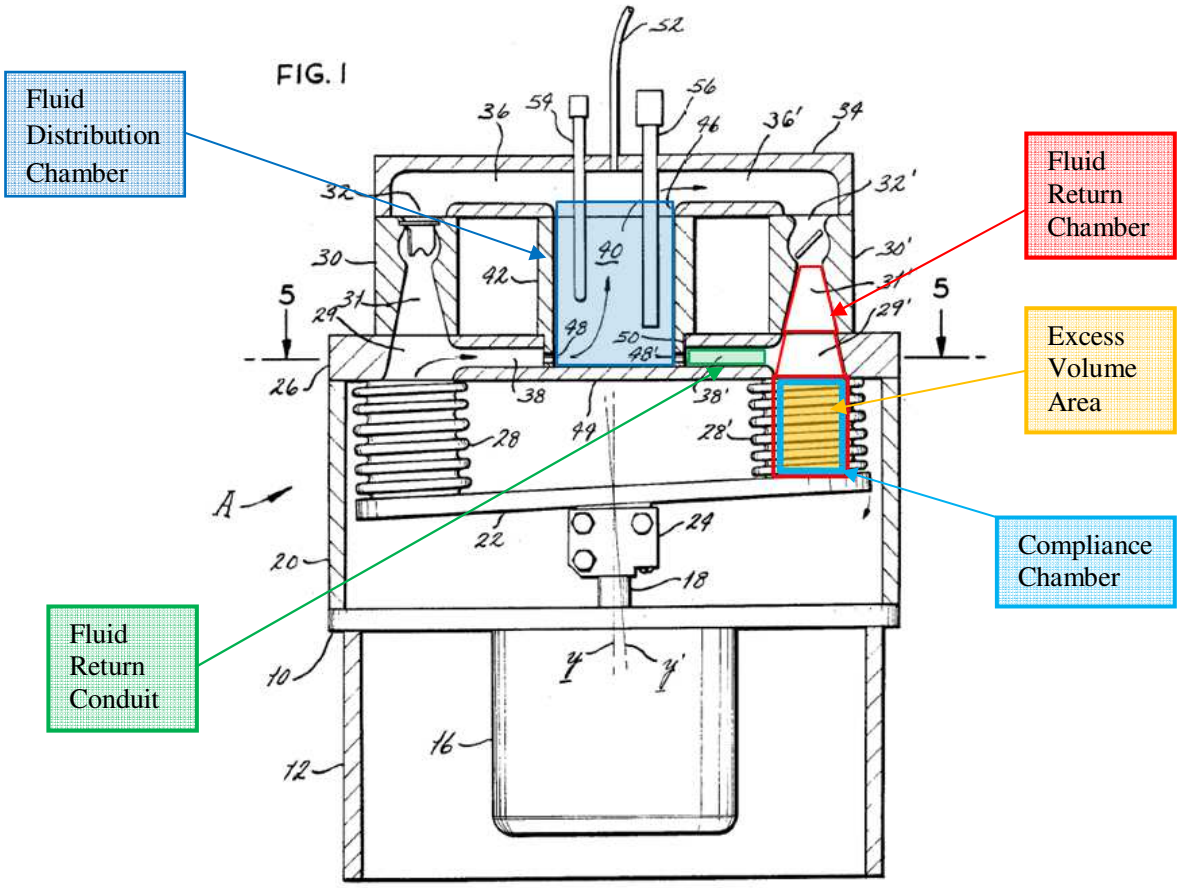

**Swanson Fig. 1**

66. System A of Swanson features a rotating swash plate which repeatedly compresses and expands bellows connected thereto. Exh. 10, Swanson, 2:21-35. As depicted in Figure 1, as a result of rotating the tilted swash plate, when bellows 28' is compressed, bellows 28 is extended. One of skill in the art would understand that, when bellows 28' is extended, bellows 28 is compressed. The bottom of the bellows are a pressure source in Swanson's System A. Exh. 10, Swanson, 4:36-38. Swanson describes a "bellows-actuated fluid oscillator for

cycling fluid at a frequency of from several hundred to several thousand cycles per minute in a completely closed liquid condition." Exh. 10, Swanson, 3:3-6. Thus, Swanson's System A features "a pressure source configured to drive a test system fluid cyclically within the device above a normal physiological rate, at an accelerated pulsed rate of greater than 200 beats per minute within the device;" as required by the first element of claim 1 of '935 patent.

67. Swanson's System A includes a chamber for receiving test samples. Exh. 10, Swanson, Fig. 1 and 2:12-20. Swanson's chamber "provides testing in a completely sealed fluid environment." Exh. 10, Swanson, 2:4-11. And according to Mr. Girard, "[i]n order for [a device] to function as a heart valve testing system, the test chamber must be pressurizable." Girard Dec., p. 11. Applying Mr. Girard's reasoning to Swanson's heart valve testing system, System A's chamber must be pressurizable. Thus, Swanson's System A features "a pressurizable test chamber for containing the test system fluid;" as required by the second element of claim 1 of '935 patent.

68. As illustrated in Figure 1, System A's fluid test environment includes a fluid distribution chamber (chamber 40), a fluid return chamber (components 31', 29', 28'), and fluid return conduits (passage 38'). Swanson's System A operates by compressing a bellows, such as bellows 28, to advance test system fluid through diametrically opposed valves along fluid path indicated by the arrows in Figure 1. When bellows 28 contracts, fluid is advanced through fluid distribution chamber (component 40) to a first side of valved prosthetic device (valve 32'). Fluid then passes through valved prosthetic device 32' into the fluid return chamber (components 31', 29', 28') positioned on a second side of the valved prosthetic device. Fluid return conduit (passage 38') structurally and fluidically connects the fluid distribution chamber with the fluid return chamber. A visual aid based on Swanson's Figure 1 follows:




**Swanson Fig. 1**

69. Mr. Girard indicates that when "test fluid is able to move from [a first component] to [a second component], … the two are 'in fluid communication.'" Girard Dec., p. 13. Applying Mr. Girard's interpretation of "in fluid communication," without adopting it or considering whether it is appropriate, the fluid distribution chamber (chamber 40) is in fluid communication with the pressure source (bottom of bellows). Thus, Swanson's System A features "a fluid distribution chamber positioned on a first side of the valved prosthetic device and in fluid communication with the pressure source;" as required by the third element of claim 1 of '935 patent.

70. Applying Mr. Girard's interpretation of "in fluid communication with," each component in System A's sealed fluid environment is in fluid communication with all of the

other components in the environment. For example, the volumes provided by either extending bellows are in fluid communication, as defined by Girard, with their respective fluid return chambers.

71. As explained above, Swanson's System A features "a fluid return chamber positioned on a second side of the valved prosthetic device; [and] a fluid return conduit both structurally and fluidly connecting the fluid distribution chamber to the fluid return chamber;" as required by the fourth and fifth elements of claim 1 of '935 patent.

72. As described earlier, a closed cyclic heart valve testing system must include a volume where the displaced fluid can be received or stored in order to allow test system fluid to be displaced (i.e., flow). The '935 Patent addresses this requirement with a "compliance chambers 135 provid[ing] [an] excess volume area for fluid to move into when the piston 114 performs a compression stroke." Exh. 4, '935 Patent, 12:4-6. In Swanson, the expanded bellows provide an excess volume area for fluid to move into. For example, as Swanson's Figure 1 illustrates, expanded bellows 28 provides a volume for storing test system fluid as compare to unexpanded bellows. Thus, Swanson provides an "an excess volume area … providing a volume for storing a volume of test system fluid" as required by the sixth and final element of claim 1 in the '935 Patent.

73. According to Mr. Girard, if a heart valve testing device "operates at an accelerated rate, … [its] excess volume area is 'capable of operating at the accelerated pulsed rate.'" Girard Dec., p. 13. Applying Mr. Girard's interpretation of an "excess volume area capable of operating at the accelerated pulsed rate," without adopting it or considering whether it is appropriate, Swanson has an excess volume area capable of operating at [an] accelerated pulsed rate because System A operates at several hundred to several thousand cycles per minute

and includes a volume for storing test fluid in in expanded bellows. Thus, Swanson's System A features "an excess volume area capable of operating at the accelerated pulsed rate," as required by the sixth element of claim 1 of '935 patent.

74. Again applying Mr. Girard's interpretation of "in fluid communication with," the volume for storing test fluid in in expanded bellows is in fluid communication with the fluid return chamber (components 31', 29', 28') because fluid is able to move from that volume to that chamber. Thus, Swanson's System A features "an excess volume area … in fluid communication with the fluid return chamber," as required by the sixth element of claim 1 of '935 patent.

75. As explained above, the test fluid in heart valve testers is generally considered incompressible. Swanson discloses "the test fluid may be sterile human blood plasma … or other suitable fluids." Exh. 10, Swanson, 3:12-16. In my opinion, one of skill in the art would understand suitable test fluids to be incompressible. In my opinion, one of skill in the art would understand that there is no compression of an incompressible fluid.

76. But Mr. Girard states that, at times, "test system fluid is under compression." Girard Dec., p. 13. In my opinion, Mr. Girard is interpreting "test system fluid … under compression" to mean "test system fluid … under pressure." Applying Mr. Girard's interpretation of "test system fluid … under compression," without adopting it, Swanson provides an "excess volume area … providing a volume for storing a volume of a test system fluid when the test system fluid is under compression," as required by the sixth element of claim 1 in the '935 Patent.

77. Additionally, I note that Mr. Girard says that a "person of ordinary skill would understand the term 'compliance chamber' to mean 'a cavity or volume that functions to absorb

some of the pressure in the system.'" Girard Dec., p. 14. In support, Mr. Girard cites part of a sentence from a patent related to the '935 patent. But Mr. Girard does not explain why he does not include the second function in the sentence as part of his definition. Whereas Mr. Girard states that "the specification notes that [the compliance chamber] may be air or another gas," it actually states that the compliance chambers 135 may merely "contain" air or another gas. Exh. 6, '538 Patent, 8:66-9:1. And the specification also states that "the compliance chambers 135 may house a porous material or an elastomeric material." Exh. 6, '538 Patent, 9:4-6. Mr. Girard also does not explain why none of BDC's statements about compliance chambers during prosecution would affect how one of skill in art would understand that term.

78. Having not had sufficient time to reach a conclusion as to the meaning of "compliance chamber" in the proper context, I reserve the right to disagree with Mr. Girard's proposed construction. Nonetheless, applying Mr. Girard's interpretation of "compliance chamber," without adopting it or concluding that it is appropriate, Swanson's bellows are a compliance chamber. When Swanson's bellows expand and store test system fluid, they absorb some of the pressure in the system. Indeed, if a first bellows did not expand and store some of the test fluid when a second bellows compressed, Swanson's System A would not be able to function, and the pressure within the system would become infinite.

79. Without addressing how BDC's statements about compliance chambers during prosecution would affect how one of skill in art would understand the term, like Mr. Girard, I note that one of ordinary skill in the art would understand a meaning of compliance to be a change in volume corresponding to a change in pressure. Swanson's bellows expand and contract in response to changes in pressure. Thus, one of skill in the art would consider Swanson's bellows, or a portion thereof, to be compliance chambers. Again, Swanson's System

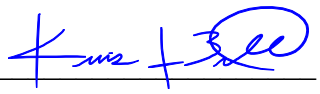
A includes a fluid return chamber (components 31', 29', 28') and the bellows is within that chamber. Thus, Swanson's System A features an "excess volume area comprises a compliance chamber defining a cavity within the fluid return chamber," as required by claim 9 in the '935 patent. Exh. 4, claim 9.

80. In my opinion, the Patent Office would not have concluded that an excess volume area "capable of operating at the accelerated pulsed rate" distinguished over the prior art if it had known Mr. Girard's interpretation. In other words, the Patent Office would not have allowed the claims if it understood that any tester including an excess volume area and capable of operating at the accelerated pulsed rate would meet the limitation.

81. As explained above, Swanson's System A includes every element of claims 1 and 9 of the '935 patent. Therefore, in my opinion, Swanson anticipates claims 1 and 9 of the '935 patent.

I declare under the penalty of perjury that the foregoing is true and correct.

Dated: December 21, 2017



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